



Application procedure for food contact materials

The application procedure is described in Regulation EC 1935/2004. The application submitted under Regulation EC 1935/2004 must be compiled according to EFSA's guidance. Applications should be submitted to the competent Authority of a Member State, which will make the application available to EFSA.

Legend:

- Applicant
- Member State Authority
- European Commission (EC)
- EFSA

Pre-submission phase

Potential applicant requests
general pre-submission advice
(optional)

Potential applicant notifies studies
commissioned or carried out as of
27 March 2021

Regulation EC 1935/2004

- Regulation EU 10/2011
- Regulation EC 450/2009
- Regulation EU 2022/1616

Applicant submits the application via
e-submission system to
Member State Authority

Member State Authority tasks
(mandate) EFSA and makes the
application available to EFSA

Receipt of the application by
EFSA and completeness check

**30
working
days***

Submission phase & completeness
check

EFSA
validates** the application

EFSA launches public consultation
on the application dossier

EFSA performs thorough
risk assessment

EFSA Panel adopts
the scientific output

**6 months +
Request of
additional
information*****

**Confidentiality
decision-making
and proactive
disclosure**

Risk assessment phase

EFSA publishes the scientific
output

Based on EFSA's opinion the EC
prepares a draft specific measure

Post-adoption phase

* EFSA aims at providing its 1st feedback on Completeness check within 30 working days after receipt of the application. In case certain parts of the application need modification or completion in order to be considered valid, EFSA requests the missing information to the applicant.

** In certain cases, the application might be declared as non-valid (see EFSA administrative guidance for further information).

*** In case of a request of additional information, the scientific risk assessment process is put on hold until the requested additional information is supplied by the applicant.